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6.0 STUDY PLAN

6.1 Design

This is a Phase III, multicenter, prospective, randomized, stratified, placebo-controlled, double-blind clinical trial

The subjects at each site will be randomized at a 1:1 ratio to one of two treatment regimens (*S aureus* vaccine or an inactive placebo)

After injection, subjects will be observed for vaccine immunogenicity (serum *S. aureus* types 5 and 8-specific IgG) and occurrence of all culture-proven *S. aureus* infections and all culture-proven *S. aureus* bacteremias until the study is closed.

active elicitation of adverse events by history and physical examination, with assessment of seriousness and relationship to the study drug, will be carried out by the sub-investigators.

6.4 *Randomization and Blinding*

Subjects will be randomized to the two treatment groups in a 1:1 ratio.

Identical-appearing vaccine and phosphate-buffered saline placebo vials will receive blinded labeling, with each vial bearing a unique numeric code,

The assignment of unique numeric codes to active vaccine or placebo will be securely retained until such times as designated by the analysis plan (section 8.0).